# EXHIBIT D

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# CADAVERIC VERSUS AUTOLOGOUS FASCIA LATA FOR THE PUBOVAGINAL SLING: SURGICAL OUTCOME AND PATIENT SATISFACTION

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ABSTRACT

Purpose: We report our initial experience with cadaveric fascia lata in pubovaginal sling procedures.

Materials and Methods: We compared 121 consecutive women who underwent a sling procedure using cadaveric fascia lata from February 1997 through June 1999 (group 1) with 46 consecutive women who underwent a sling procedure using autologous fascia lata from May 1994 through July 1997 (group 2).

Results: Mean followup was longer in group 2 (44 versus 12 months). A total of 104 of the 121 group 1 patients (86%) responded to the questionnaire, of whom 85% were cured of stress incontinence, 83% reported overall improvement in urinary control and 74% had no or minimal leakage not requiring pads. Median catheterization time was 9 days (range 4 to 120). Overall 89% of the women were satisfied with the results and 83% would recommend this surgery. A total of 30 of the 46 group 2 patients (65%) responded to the questionnaire, of whom 90% were cured of stress incontinence, 90% reported overall improvement in urinary control and 73% had no or minimal leakage not requiring pads. Median catheterization time was 14 days (range 6 to 180). Overall 90% of the women were satisfied with the results and 83% would recommend this surgery.

Conclusions: Cadaveric fascia lata pubovaginal slings appear to be safe. Early experience suggests that cadaveric fascia lata may be considered an alternative to autologous fascia. Cadaveric and autologous fascia lata appear to have a high success rate.

KEY WORDS: lata, fascia; urinary incontinence; bladder; cadaver; transplantation, autologous

The pubovaginal sling procedure has become the gold standard for treating intrinsic sphincteric deficiency and stress urinary incontinence in women.[1] Initially described in 1907, the first sling procedure used gracilis muscle to encircle the urethra[2] but the procedure was extensively modified with time. As the procedures have evolved, so has the choice of sling materials. Current options include autologous rectus fascia or fascia lata, synthetic materials such as polytetrafluoroethylene, silicone, polypropylene and polyester, and cadaveric fascia lata, dura and dermis.

Each material harbors certain risks and benefits. When harvested from the abdominal wall or thigh of the patient, autologous fascia adds to operative time and incurs a risk of hematoma, wound infection, herniation and patient discomfort.[3] Synthetic materials are associated with erosion and an infection rate as high as 23% with polytetrafluoroethylene slings.[4] Chronic local complications, including sinus tracts, fistulas and wound infection, have also been reported with synthetic materials.[5]

Allografts are tissues harvested from a human donor, usually a cadaver, and transplanted into a human recipient. They have been used in clinical practice for more than 20 years and are safe and stable with time.[6] After implantation the local response to allogenic cadaveric fascia is no different than that to autologous fascia.[7] Therefore, cadaveric fascia should provide the same advantages as autologous fascia in pubovaginal sling procedures but without the potential complications and morbidity associated with the intraoperative harvesting of autologous fascia.

We report our early experience with consecutive patients who received cadaveric fascia lata and compare those results to those in an earlier consecutive group in which we used autologous fascia. This interim review may guide our choice of graft material in the future. As with other sling materials, we believe that most local complications[4] and failures[8] should be apparent within the initial 6 to 12 months.

## MATERIALS AND METHODS

We compared 121 consecutive women who underwent a pubovaginal sling procedure using cadaveric fascia lata from February 1997 through June 1999 (group 1) to 46 consecutive women who underwent such a procedure using autologous fascia lata from May 1994 through July 1997 (group 2). There were no selection criteria in the 2 groups other than the gradual change to cadaveric fascia lata in early 1997. Each patient was evaluated by a focused history and physical examination, voiding diary, cystoscopy and video urodynamic study. We reviewed the hospital and clinical records. In addition, we mailed a detailed survey questionnaire to all patients that was similar to a previously published questionnaire of Haab et al (see Appendix).[9]

We compared preoperative parameters in groups 1 and 2, including patient age, the incidence of previous incontinence procedures and associated pelvic surgery using the same anesthetic, the severity and type of incontinence, and abdominal leak point pressure (see table). The technique used to determine abdominal leak point pressure was unchanged from that of an earlier study.[10] In 112 cases (93.5%) the pubovaginal sling was constructed using a continuous 2 × 24

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*Preoperative patient characteristics*

| | Group 1 | Group 2 |
|---|---|---|
| Mean pt. age (yrs.) | 62 | 62 |
| % Previous incontinence procedures | 42 | 73 |
| % Associated pelvic surgery | 34 | 10 |
| % Incontinence degree: | | |
| Mild | 31 | 12 |
| Moderate | 36 | 24 |
| Severe | 33 | 64 |
| % Incontinence type: | | |
| Pure stress | 50 | 35 |
| Mixed | 50 | 65 |
| Mean leak point pressure (cm. water) | 42 | 29 |

to 28 cm. strip of cadaveric fascia lata obtained from our local tissue bank. In 9 cases (7.5%) the fascial strip was too short to construct a continuous sling, and so we suspended a 2 × 9 cm. strip from the rectus fascia with No. 1 polypropylene sutures.

Figure 1 shows our standard procedure for constructing a pubovaginal sling using autologous fascia lata, as reported previously.[10] However, we have modified the technique. In all patients a 12Fr suprapubic catheter was placed at surgery, which was used until post-void residual urine volume was less than 100 cc. We also modified our earlier method of adjusting sling length or tension. With all vaginal retractors removed but a urethral Foley catheter in place and 2 small self-retaining retractors remaining in the suprapubic region, we elevated each end of the sling, let them fall into a neutral position and tacked them to each other with 2 interrupted polypropylene sutures. If lifting the sling from above and releasing it revealed any tension on the anterior abdominal wall or traction on the Foley catheter demonstrated that the urethra was fixed too high, the sutures were cut and the sling adjusted with less tension (fig. 1, *A*). When the proper length was achieved, the sling was tacked to itself with 4 polypropylene sutures (fig. 1, *B*). Postoperatively we mailed all patents a detailed survey questionnaire adapted from Haab et al (see Appendix).[9] Chart review and patient survey were done by a physician not associated with the original procedures.

## RESULTS

We noted no significant difference in surgical outcome and the patient satisfaction in cadaveric fascia lata and autologous fascia lata groups. However, mean followup was shorter in group 1 (12 months versus 44 months). Of the 121 group 1 patients 104 (86%) responded to the questionnaire, including 88 (85%) who were cured of stress incontinence and 86 (83%) with overall improvement in urinary control. Based on questionnaire results 77 of the 104 cases (74%) were considered cured, defined as no or minimal leakage not requiring pads; 20 (19%) improved, defined as 1 to 3 pads used daily; and 7 (7%) failed, defined as more than 3 pads used daily. Figure 2 shows the results of the patient survey questionnaire in group 1. Median duration of clean intermittent catheterization or suprapubic tube drainage postoperatively was 9 days (range 4 to 120). Complications in group 1 were rare, involving prolonged urinary retention in 2 cases, a suprapubic abscess in 2, lower extremity neuropathy in 1 and suprapubic hematoma in 1. Overall 93 of the 104 women (89%) who underwent a cadaveric fascia lata pubovaginal sling procedure were satisfied with urinary control and would undergo the procedure again, while 86 (83%) would recommend this surgery to a friend.

Of the 46 group 2 patients 30 (65%) responded to the questionnaire, including 27 (90%) who were cured of stress incontinence, 27 (90%) with overall improvement in urinary control, 22 (73%) considered cured with no or minimal leakage not requiring pads and 8 (27%) improved. There were no failures, defined as more than 3 pads used daily (fig. 3). Median duration of catheterization or suprapubic tube drainage was 14 days (range 6 to 180). Complications in group 2 involved prolonged urinary retention in 3 cases, a cerebrovascular accident in 1 and persistent thigh pain at 6 weeks in 5 (11%). One woman in prolonged urinary retention required urethrolysis. Overall 27 of the 30 patients (90%) who underwent the pubovaginal sling procedure using autologous fascia lata were satisfied with urinary symptoms and would undergo the procedure again, while 25 (83%) would recommend this surgery to a friend. As expected, mean operative time was significantly shorter in group 1 (82 versus 129 minutes) because fascia was not harvested and patients were not repositioned.

Although no objective instruments were used to measure pain postoperatively, the difference in the 2 groups was dramatic. Virtually all patients in the autologous group had thigh pain at 1 to 2 weeks and 5 (11%) described persistent thigh pain at 6 weeks. No thigh pain was noted in the cadaveric group and only 1 patient (0.9%) had persistent suprapubic pain at 6 weeks.

## DISCUSSION

Soft tissue allografts have been placed for many years but allogenic tissue initially gained acceptance in clinical practice in the early 1980s.[6] The most established use of fascia lata allografts is in reconstructive orthopedic procedures.[6] Cadaveric donor fascia is processed by licensed tissue banks regulated by the Food and Drug Administration.[11] The antigenicity of soft tissue allografts is eliminated by freezing and freeze-drying,[6] so

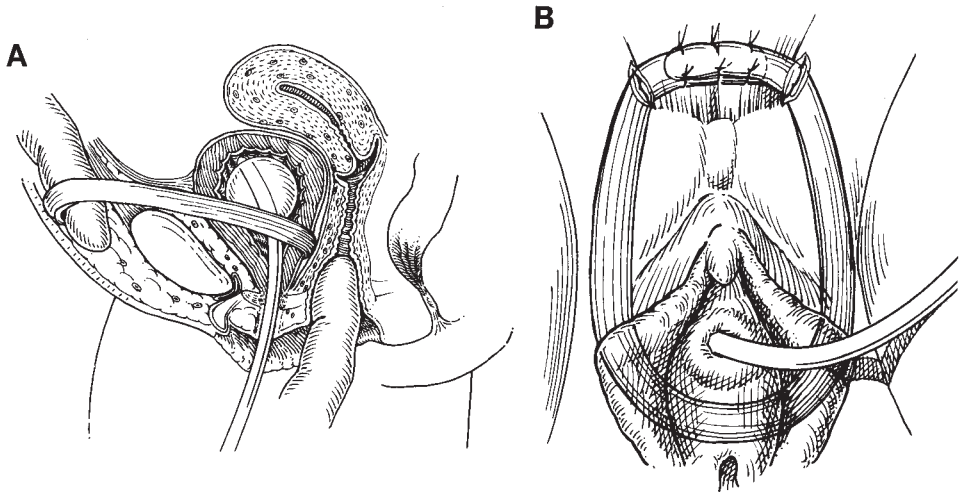


FIG. 1. *A*, adjusting sling tension. *B*, sling attached to itself. Reprinted with permission[10]

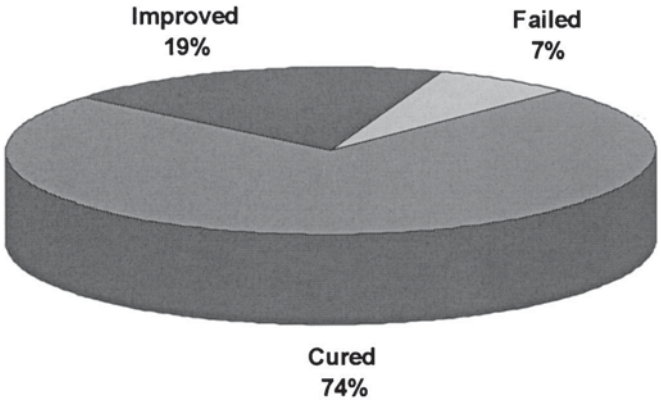


FIG. 2. Results of group 1 patient survey questionnaire

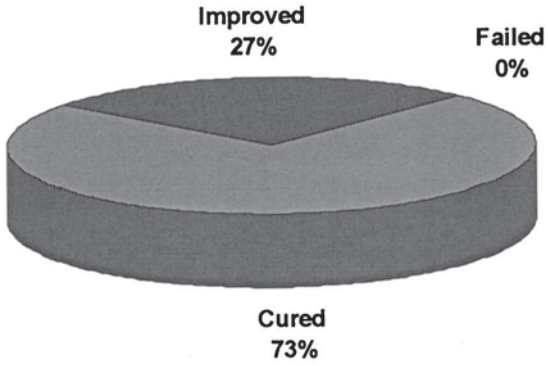


FIG. 3. Results of group 2 patient survey questionnaire

that donor and recipient matching is not needed. To our knowledge no rejection response has been reported after frozen or freeze-dried allograft transplantation.

An important issue concerning the use of cadaveric fascia lata is the potential for transmitting infectious disease, such as hepatitis and HIV. All licensed tissue banks are required to screen donors for HIV and other viruses. To minimize risk allograft fascia is carefully sterilized and processed to reduce the graft to an acellular fibrous mesh, which is sufficient to inactivate known viruses. The risk of HIV transmission from soft tissue allografts has been estimated as 1/8 million cases.[12] Simonds et al documented the only known case of HIV transmission due to tissue transplantation, which developed in a woman after she received a bone allograft from a seronegative tissue donor.[13]

Another potential risk of cadaveric fascia transplantation is the transmission of so-called prion disease. Prions are proteinacious infectious particles that harbor infection within a host protein. Prions do not illicit a host response but they are believed to elicit a response in recipients. Prions may be the causative agent of transmissible spongiform encephalopathy, of which the most common is Creutzfeldt-Jakob disease. The prion agent is highly resistant to treatment that damages or destroys nucleic acids, such as ultraviolet radiation and nuclease, but it may be inactivated by exposure to treatment that destroys or denatures protein, such as chaotropic ions or denaturing detergents.[14] Although the risk of prion disease from blood products or other biological agents is now a focus of worldwide concern,[14] our extensive review of the literature failed to document any transmissible spongiform encephalopathy associated with cadaveric fascia lata.

Cadaveric fascia seems to be a welcome addition to the many materials used for pubovaginal slings since allografts have been shown to be safe and efficacious in orthopedic studies. Cadaveric fascia lata is reliably robust with acceptable quality. No additional surgery is necessary to obtain the graft, which saved 47 minutes of operative time per patient in our cadaveric group. Because there was no thigh dissection, we noted a dramatic decrease in postoperative pain early and at 6 weeks. Wright et al also reported decreased operative time and morbidity as well as an outcome similar to that of autologous fascia slings after changing from autologous rectus fascia to autologous fascia lata.[15]

We hypothesized that the cure rate of the cadaveric fascia lata pubovaginal sling would be similar to that in our previous experience with the autologous fascia lata pubovaginal sling. In our comparative study 85% of women were cured of stress incontinence in the cadaveric fascia lata group compared with 90% in the autologous fascia lata group. Furthermore, the overall 74% cure rate in the cadaveric fascia lata group was almost identical to the 73% overall cure rate in the autologous fascia lata group. The cure rate in each group is similar to those previously published for autologous and synthetic materials.[8,9,15–19] The finding that causes some concern is the 7% failure rate in the cadaveric versus 0% in the autologous group.

The table shows that groups 1 and 2 patients were different. Group 2 patients had undergone more anti-incontinence procedures, and had more severe incontinence, more mixed incontinence and lower leak point pressure. Our initial experience with the pubovaginal sling procedure using autologous fascia lata in group 2 primarily involved the treatment of incontinence secondary to intrinsic sphincteric deficiency. More straightforward stress incontinence was managed by modified Pereyra needle suspension. As more data became available on the success of the pubovaginal sling procedure and the poor long-term results of needle suspension, we began to create slings in women with each type of incontinence.[16,18] Thus, group 1 comprised more women with genuine stress incontinence, higher leak point pressure and more associated pelvic procedures for relaxation.

Although mean followup was shorter in the cadaveric than in the autologous fascia lata group (12 versus 44 months), most failures[8] and local complications[4] associated with other sling materiels manifested within this postoperative window. As others reported,[18,19] we also observed that most surgical failures for stress incontinence after a sling procedure presented within the initial 3 months. Patients in whom slings failed often never achieved dryness or reported feeling something come loose within month 1 postoperatively.[18] Slings typically fail due to too much or too little tension, suture breakage, disruption of the sling or failure to place the sling into the retropubic space, where it becomes fixed. Such problems present soon after surgery before the sling scars in the retropubic space.[18] Of our 7 patients in whom a cadaveric fascia lata pubovaginal sling failed 5 were never dry and 2 were dry for only 1 month, while treatment was not considered to have failed in any of the autologous fascia lata group.

Many variables must be considered in regard to the 7% failure rate in our cadaveric group. As our series progressed and more patients with pure anatomical descent versus intrinsic sphincteric deficiency were treated, we placed less tension on the sling. Did we err by making the slings too loose? FitzGerald et al reported cadaveric sling autolysis.[20] To date reoperation has not been performed in any of our failed cadaveric cases. Instead we have opted to treat them with periurethral injection. Baseline urinary leakage in the cadaveric group was less severe. Is the failure rate in this group a factor of how improvement and failure were defined? In groups 1 and 2 the cure rate was identical at 74% and 73%, respectively. At this time we believe that our numbers are too small and variability too great to make a definitive statement. Longer followup, larger numbers and better matched control groups may answer this question in the future.

Prolonged urinary retention, defined as greater than 50 days, developed in 2 women who received a cadaveric fascia lata graft. Urodynamics revealed an areflexic detrusor in 1

woman, who voided by abdominal straining. Of the 3 patients in the autologous fascia lata group with prolonged urinary retention 2 had low and 1 elevated detrusor pressure, requiring sling incision. We discharged patients home early on the morning after surgery, and so all had a suprapubic tube indwelling to measure post-void residual urine. When post-void residual urine volume was less than 100 cc, suprapubic tube was typically removed at the 1-week followup visit. Thus, many patients who recorded suprapubic drainage for 1 week may have used the suprapubic tube for only 1 or 2 days. Nevertheless, in our study the median duration of suprapubic catheterization and the number of patients in prolonged urinary retention compare favorably with the results of other published series.[8,9,18,21] Although cost was not specifically evaluated, the cost of cadaveric fascia lata obtained from our local tissue bank is approximately $220 to $400 for a piece large enough to fashion a 2 × 24 to 28 cm. graft. This cost is somewhat higher than that of synthetic material[21] but less than that of commercially available cadaveric fascia.

Patient questionnaires have been shown to indicate a worse outcome than chart review for various reasons, including incomplete followup, physician and/or patient bias, and patient and physician perception or misperception of the definition of a successful result.[10] Haab et al reported that administering a patient questionnaire facilitates the accurate assessment of outcome after anti-incontinence procedures but to our knowledge there is no suitable validated patient questionnaire for assessing results and patient satisfaction after pubovaginal sling procedures.[9] We administered a questionnaire similar to that previously used by Haab et al, and believe that it is reliable and accurate.

## CONCLUSIONS

Cadaveric fascia lata pubovaginal slings appear to be safe and are associated with no risk of disease transmission. Until we can definitively test for prion disease we continue to counsel all patients in regard to the theoretical risk of disease transmission. The early failure rate in a small number of cadaveric fascia lata cases requires further study. However, overall surgical results and patient satisfaction with cadaveric fascia lata appear equal to those of autologous fascia. Operative time and postoperative pain were significantly decreased in the cadaveric group. If these results remain consistent at longer followup, we believe that cadaveric fascia lata may become the material of choice for constructing pubovaginal slings.

## APPENDIX: QUESTIONNAIRE

1. Had you undergone previous operations to correct urinary incontinence or lift the bladder prior to your sling operation?
   A. Yes
   B. No
2. If yes, how many? _____
3. How much leakage did you have before the sling operation?
   A. Leakage on rare occasion, no pads
   B. 1 to 3 small pads per day
   C. Several small to medium pads per day
   D. Multiple large pads or diapers
4. How much leakage of urine do you have now?
   A. None
   B. Very little (leak on rare occasions not requiring pads)
   C. Moderate (1–3 pads/day)
   D. Severe
5. If you do leak urine, how does it usually occur?
   A. Mostly with coughing, sneezing, or physical activity
   B. Usually not with physical activity, but leakage occurs suddenly before it can be controlled
   C. Leakage of urine often occurs in both of the situations described
   D. Not sure when leakage occurs
6. How much improved is your urine leakage now compared to before the surgery?
   A. 100% better
   B. 90% better
   C. 80% better
   D. 70% better
   E. 60% better
   F. 50% better
   G. 40% better
   H. 30% better
   I. 20% better
   J. 10% better
   K. The same
   L. Worse than before surgery
7. Do you now wear any protection from urine leakage (pads and so forth)?
   A. Yes
   B. No
8. If you are wearing pads, how many do you use in a 24 hour period? _____
9. What type of pads?
   A. Small (liner)
   B. Moderate (Kotex)
   C. Large (Attends)
10. How often do you urinate during the day?
    A. More often than once every hour
    B. Every 1–2 hours
    C. Every 3–4 hours
    D. Less often than once every 4 hours
11. How many times per night do you wake from sleep to urinate?
    A. None
    B. 1
    C. 2
    D. 3
    E. More than 3
12. Pick the response that best describes "how you start your flow."
    A. Easy
    B. Sometimes difficult
    C. Wait less than one minute to start flow
    D. Wait more than one minute to start flow
    E. Have to push or strain
    F. Impossible
13. Do you currently use a catheter to empty the bladder?
    A. Yes
    B. No
14. If your incontinence returned after sling surgery, how long were you dry?
    _____ months
15. Overall, how satisfied are you with the results of your sling surgery?
    0 1 2 3 4 5 6 7 8 9 10
    Not satisfied Very satisfied
16. Knowing what you know now, would you have the sling surgery again?
    A. Yes
    B. No
17. Would you recommend the sling surgery to a friend?
    A. Yes
    B. No
    C. Not sure

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## EDITORIAL COMMENTS

Clearly the pubovaginal sling is the most successful and durable treatment modality for women with type II or III stress urinary incontinence. What remains unclear is whether success depends on the material chosen for the sling. Initially many were led to believe that minimally invasive techniques using a synthetic sling would provide an equal outcome while decreasing the morbidity associated with autologous fascia harvesting. Due to an unacceptably high incidence of complications most have abandoned the use of synthetic material for pubovaginal sling.

In a nonrandomized retrospective manner the authors compared their short-term 12-month experience with cadaveric versus autologous fascia lata. Cadaveric fascia decreased operative time and postoperative pain, while providing comparable questionnaire generated cure and satisfaction rates. Appropriately and concisely the authors reviewed the proved safety record of cadaveric tissue yet it is imperative to counsel our patients regarding the long-term uncertainty of potentially undetectable infectious agents.

The authors noted with only mild concern that patients who received cadaveric fascia had a significantly higher short-term complete failure rate of greater than 3 pads daily. This difference of 7% versus 0% is worrisome and it occurred although those patients had less severe preoperative incontinence and higher leak point pressure. Does this finding add to the theory of early autolysis of donor fascia or are patients with hypermobility better served by autologous fascia, which may provide more strength in the immediate 1 to 3 months postoperatively?

Based on previous studies of autologous fascia it appears that patients with no stress incontinence 1 year after a pubovaginal sling procedure rarely have recurrence in the subsequent 10 years.[1,2] Therefore, the opinion of the authors that comparable outcome in the groups at 1 year predict a comparable long-term outcome may be justifiable. Before accepting this opinion as a conclusion we should wait for the maturity of these data and those of similar series.

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The acceptance of slings for stress incontinence has accelerated in recent years. This series exemplifies the trend toward an increasing use of slings in all such cases. The authors report a nonrandomized, retrospective, questionnaire based control study comparing cadaveric with autologous fascia lata as the sling material. The groups compared were relatively unselected since the fascia lata series was an earlier consecutive series than the cadaveric fascia group. The data indicate that a less morbid technique may be associated with similar efficacy.

Thigh pain was a problem in the fascia lata group. Most patients had short-term pain and a small group had pain for longer than 6 weeks. Harvesting fascia lata added a significant time burden. Low wound related morbidity in the cadaveric group encouraged the authors to abandon the use of autologous fascia.

Other studies comparing cadaveric to autologous fascia have shown comparable results (reference 15 in article). Are we ready to discard autologous fascia and move to cadaveric fascia exclusively? Cadaveric fascia appears to be promising but there is some cause for concern. In this series a group of outright failures is unexplained. Short-term failure is rare in series in which native tissue is used. Whether the processing of the cadaveric fascia, performed to decrease its infective risk, also decreases its effectiveness as a pseudoligament remains to be determined. Further laboratory based and clinical research is required to answer such a question. Especially if the morbidity rate with autologous fascia is low, the small but uncertain risk of entities such as prion infection and concerns about efficacy support the ongoing use of a minimally morbid autologous technique. The thigh complications reported in this study would appear to be unique to fascia lata grafts. When small rectus fascia grafts are harvested, it appears that no such complications occur.[1] Some patients do not have suitable rectus fascia because mesh was used to repair an abdominal hernia or because of other factors. Cadaveric fascial slings appear to be safe, reasonably effective and particularly useful when an autologous graft is likely to be difficult to obtain.

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